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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,605	02/21/2002	Thomas Keast	435712003521	7676

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BRNCUS TECHNOLOGIES, INC.  
BUILDING A8  
1400 N. SHORELINE BLVD.  
MOUNTAIN VIEW, CA 94043

EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/079,605

Applicant(s)

KEAST ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 4,7-10,12,17 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,11,13-16,18-21 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5,7,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

This application contains claims directed to the following patentably distinct species of the claimed invention: Species #1 characterized by figures 8A-8C, Species #2 characterized by figures 2A and 2B, Species #3 characterized by 6A and 6B, Species #4 characterized by figure 4A, Species #5 is characterized by figure 4B, Species #6 is characterized by figure 4C, Species #7 is characterized by figure 4D, Species #8 is characterized by figure 5A, Species #9 is characterized by figure 5B, Species #10 is characterized by figure 5C, Species #11 is characterized by figure 5D and Species #12 is characterized by figure 5E.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant's election without traverse of Species #2 in Paper No. 13 is acknowledged.

Claims 4, 7-10, 12, 17 and 22-26 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 6, 11, 13-16, 18-21, and 27-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7, 11, 20, 27, 28, 36, 37, 48, 51, 52, 56 of copending Application No. 10/080,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims contain the same structural features and/or limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 11, 13, 18-21, 27, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Colley et al. (USPN 4,319,580).

Regarding claim 1, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a transducer assembly comprising a covering (76), at least one transducer (52) located towards the distal end of the elongate member and having at least a first (inner surface of annular ring 74) and second (outer surface of annular ring 74) pole, a first conductive medium (74) in contact with the first pole of the transducer and extending to at least a portion of an outer surface of the covering (76), at least two conducting members extending through at least a portion of the elongate member, at least a first conducting member (62A) coupled to the first conductive medium, a second conducting member (62B) extending through the proximal end of the covering and electrically coupled to the second pole of the transducer, and a

hollow conductive member (78) located at the distal end of the elongate member and electrically coupled to an electrical energy source, see col. 5-9 and figures 2, 4, 7 and 8.

Regarding claims 2 and 5, Colley et al. further disclose a tip (54B) having a round front (54B') and a back (small annular surface connecting portions 54A and 54C) surface, wherein the tip is located at the distal end of the elongate member, see beginning on col. 8, line 11 and ending on col. 9, line 30 and figures 7 and 8.

Regarding claim 11, Colley et al. further disclose that the elongate member comprises an insulating material (58). Colley et al. disclose an embodiment having a flexible tubing (58 of figures 7 and 8) made of Tygon, a plastic which is electrically insulative, see col. 8, lines 48-54.

Regarding claim 13, Colley et al. further disclose an outer sheath (58) defining a lumen inside which the elongate member is located, see col. 8, lines 48-54 and figures 7 and 8.

Regarding claim 18, Colley et al. further disclose first and second conducting members that are electrically connected to a control unit to recognize and/or measure the Doppler shift between the transmitted and received signals. Colley et al. do not explicitly recite a control unit, but they do recite "a pulsed Doppler circuit (FIG. 9) energizes the transducer and provides a Doppler signal from return signals generated by the transducer as a result of returns of transmitted ultrasonic energy. A circuit (FIGS. 10 and 11) processes the

Doppler signal,” see abstract. Also the circuitry and controls shown in figures 9-11 are inherently part of a control unit which is inherently coupled to the first and second conducting members disclosed by Colley et al. in order to provide the Doppler information.

Regarding claim 19, Colley et al. further disclose that the transducer is in the form of a piezoelectric transducer, abstract and col. 8, lines 32-39 and figures 7 and 8.

Regarding claims 20 and 21, Colley et al. further disclose that the covering comprises a first conductive tube (76), see col. 8, lines 32-39 and figures 7 and 8.

Regarding claim 27, Colley et al. further disclose that the hollow conductive member is fixed with respect to the transducer assembly, see figure 7.

Regarding claim 30, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a transducer means (74) located towards the distal end of the elongate member, a energy directing means (52) for directing the source signal and the reflected signal (see specifically the “omnidirectional” ability cited in col. 8, lines 31-62), a first conducting member (62A) coupled to the transducer means, a second conducting member (62B) coupled to the transducer means, wherein the first and second conducting members extend from the proximal portion of the elongate member to the distal portion of the elongate member. Finally, an energy-

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conducting means located exterior to the transducer means and the directional means is inherently part of the Colley et al. disclosure, since the can not function without it, see col. 5-9 and figures 2, 4, 7 and 8.

Regarding claim 31, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a ultrasonic transducer (52) located towards the distal end of the elongate member, an acoustically transmitting material (54) distal to the transducer, and a hollow conductive member (56) located at the distal end of the elongate member and circumferentially disposed about at least a portion of the elongate member, see col. 5-9 and figures 2, 4, 7 and 8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, 13-15, 18-21 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (USPN 5,316,001) in view of Webster, Jr. (USPN 5,916,158).



Regarding claims 1, 14, 15, 19, 20, 21 and 30, Ferek-Petric et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (280), a transducer assembly comprising a covering (285) comprising a first conductive tube, at least one piezoelectric transducer (283) located towards the distal end of the elongate member and having at least a first (bottom surface of annular ring comprising the piezoelectric material of transducer 283) and second (top surface of annular ring comprising the piezoelectric material of transducer 283) pole, a first conductive medium (interior of annular ring comprising the piezoelectric material of transducer 283) in contact with the first pole of the transducer and extending to at least a portion of an outer surface of the covering (285), at least two conducting members extending through at least a portion of the elongate member, at least a first conducting member (281) coupled to the first conductive medium, a second conducting member (289) extending through the proximal end of the covering and electrically coupled to the second pole of the transducer, and a round tipped conducting member or pacing electrode (not shown but analogous to that of 101 in figure 10) located at the distal end of the elongate member and electrically coupled to an electrical energy source (it is inherently connected to an electrical energy source since it provides a pacing signal for the heart), see abstract and beginning on col. 11, line 45 and ending on col. 12, line 36 and col. 17, lines 10-41 and figures 9, 10 and 15. Ferek-Petric et al. further disclose a third conducting member (282) connected to pace lead electrode, see col. 17, lines 10-41 and figure 15. Ferek-Petric et al. also disclose an energy directing means or "lens" (293) for directing the transmitted and received ultrasound waves, see col. 17, lines 10-41 and

figure 15. Ferek-Petric et al. are silent as to whether the conductive member is hollow or not. Ferek-Petric et al. also fail to disclose the hollow conducting member is connected to an RF energy source. However, it is well known in the art to provide an alternative hollow conductive electrode for the pacing lead as demonstrated by Webster, Jr., see col. 6, lines 25-67 and figures 6-13 and 16, wherein the hollow conducting member is element (33) the cup electrode. Additionally, Webster, Jr. suggests the use of a catheter having electrodes capable of performing multiple functions such as ablation, pacing, electrograms, stimulation impedance measurements and mapping, see col. 2, lines 22-44. Webster also discloses that the electrodes are coupled to an RF source in order to provide ablation energy, see col. 3, lines 10-18 and col. 9, lines 13-29. This provides the motivation for connecting the pacing lead of Ferek-Petric et al. to an RF energy source in order to provide multiple functions to the electrode. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ferek-Petric et al., as is well known in the art and demonstrated by Webster, Jr. to provide an alternative hollow electrode and as further taught by Webster, Jr., to provide the electrodes with multiple functions in order to simultaneously perform these multiple functions wherein the electrodes are connected to an RF energy source.

Regarding claims 11 and 13, Ferek-Petric et al. disclose the claimed invention, see col. 17, lines 42-49.

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Regarding claim 18, Ferek-Petric et al. disclose the claimed invention. The entire reference is directed to measuring and detecting Doppler shift of the ultrasound transmitted and received signal, see abstract and co. 1-5 and figure 14D.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al.

(USPN 5,316,001) in view of Webster, Jr. (USPN 5,916,158) as applied to claim 1 above, and further in view of being well known in the art as shown by Gross (USPN 5,042,981) and Laufer et al. (USPN 6,135,997).

Regarding claim 16, Ferek-Petric et al. disclose the claimed invention except for explicitly disclosing that the hollow conducting member is made from a material from the group consisting of stainless steel, aluminum and titanium. It is very well known in the art to make components of surgical devices that come in contact with the skin from materials that are biocompatible, such as stainless steel as shown by Laufer et al. (element 12) col. 10, lines 12-24 and col.13, lines 11-46 and aluminum which also nonallergenic by Gross (element 3) col. 5, lines 44-51. The rounded tip conductive member contacts the skin and therefore is would be made of stainless steel or aluminum. Therefore, at time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ferek-Petric et al., as is well known in the art and shown by Laufer et al. and Gross, to make the rounded tip conductive member from stainless steel or aluminum in order to be compatible with the body.

*Conclusion*

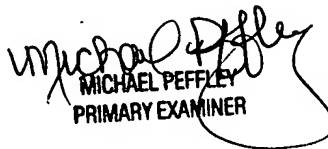
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Both Tu (USPN 6,235,024) and Suorsa et al. (USPN 6,206,831 B1) disclose a dual RF electrode/ultrasound transducer catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R.  
September 26, 2003

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER